REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. Status of the Claims

Claims 2 and 4-6 are currently pending in the application.

Claim 2 is amended to delete the recitation of functional variants and specify that the isolated nucleic acid molecule comprises a polynucleotide having SEQ ID NO: 47. Support for the amendment to claim 2 can be found, *inter alia*, in claim 2 as previously presented.

Claim 4 is amended to specify that the isolated polynucleotide comprises a sequence which is complementary to SEQ ID NO: 47 or is a reverse complement sequence to SEQ ID NO: 47. The complementary sequence and the reverse complement sequence to SEQ ID NO: 47 are at least 30 nucleotides in length and confer vascular-preferred polynucleotide transcription. Support for the amendment to claim 4 may be found, *inter alia*, in claim 4, as previously presented.

These amendments do not introduce any new matter into the application and their entry is respectfully requested.

Claims 1. 3 and 7-20 were previously cancelled without prejudice to or disclaimer of the subject matter therein.

II. The Rejections Under 35 U.S.C. § 112, First Paragraph

A. Written Description

The Office Action, at pages 2-4, maintains the rejection of claims 2 and 4-6 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Office Action states that the disclosure in the specification of SEQ

ID NO: 47 does not adequately describes the genus that encompasses the functional variants of SEQ ID NO: 47, and the polynucleotides that are complementary sequences or reverse complement sequences to the functional variants of SEQ ID NO: 47. Applicants respectfully traverse this ground of rejection.

The Federal Circuit has recently clarified the law regarding written description in *Faulkner-Gunter Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006). Specifically, the court held:

> 1) examples are not necessary to support the adequacy of a written description, 2) the written description standard may be met even when actual reduction to practice is absent; and 3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.

Id., at 1366. The Federal Circuit clarified issues particularly relevant for this application. The court favorably cites *LizardTech Inc. v. Earth Resource Mapping, PTY Inc.*, 424, F.3d 1336 (Fed. Cir. 2005), explaining that the specification is written for a person skilled in the art and it is unnecessary to spell out every detail of the invention, only enough is required to convince a person of skill in the art that the inventor possessed the invention and to enable the person to make and use the invention without undue experimentation. *Id.*

The court further clarifies, as provided in *Capon v. Eshlar*, 418 F. 3d 1349 (Fed. Cir 2005), that "the 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." The court also clarifies that "an actual reduction to practice is not required for written description." *Faulkner*, at 1366. Proof of reduction to practice is not required in every case. "Thus, to the extent that written description requires a showing of "possession of the invention", Pfaff makes clear that an invention can be "complete " even when an actual reduction to practice is absent."

525 U.S. 55, 66 (1998). "The logical predicate of "possession" is, of course, "completeness."" *Faulkner*, at 1367.

With regards to recitation of known structure, Faulkner explicitly holds: "it is the binding precedent of this court that Eli Lilly does not set forth a per se rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art." *Id* .

Additionally, the Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, first paragraph, "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001) ("Guidelines"), state that the written description requirement can be met by "*showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics [...] i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.*" Guidelines, 66 Fed. Reg. at 1106.

In the current application, Applicants have sufficiently disclosed the invention to meet the written description requirement in line with the reasoning provided by the Federal Circuit.

Furthermore, solely to advance prosecution, and not in acquiescence with the rejection, Applicants have amended claim 2 to delete the recitation of functional variants of SEQ ID NO: 47, and specify that the isolated nucleic acid molecule comprises a polynucleotide having SEQ ID NO: 47. Further, Applicants have amended claim 4 to specify that the isolated polynucleotide comprises a sequence which is complementary to SEQ ID NO: 47 or is a reverse complement sequence to SEQ ID NO: 47. The complementary sequence and the reverse complement sequence to SEQ ID NO: 47 are at least 30 nucleotides in length, and confer vascular-preferred polynucleotide transcription.

Thus, the presently claimed invention is directed to an isolated nucleic acid molecule comprising a polynucleotide having the SEQ ID NO: 47 or a sequence that is complimentary to

SEQ ID NO: 47, or is a reverse complement sequence to SEQ ID NO: 47 and is at least 30 nucleotides in length, and confers vascular-preferred polynucleotide transcription. As such, the sequences claimed in the present application are defined by their sequence structure and by their function, and therefore the claims meet the written description requirement. Accordingly, the rejection is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

B. Enablement

The Office Action, at pages 4-6, maintains the rejection of claims 2 and 4-6 under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claimed invention. Specifically, the Office Action recognizes that the specification provides enablement for the isolated nucleic acid molecule of SEQ ID NO: 47. Nevertheless, the Office Action alleges that the specification does not provide enough guidance with regard to variants of SEQ ID NO: 47, and the identity and location of key nucleotides and regulatory regions in the variants required to confer vascular-preferred polynucleotide transcription. Applicants respectfully traverse this ground of rejection.

The M.P.E.P., section § 2164.08, states the following with regard to enablement commensurate in scope with the claims:

> The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without `undue experimentation'." *In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)*. Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991)*. All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the

> claims. *See, e.g., In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).*

With regard to the breadth of a claim, the M.P.E.P. states:

> As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *In re Moore, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971).*

In the current application, Applicants have sufficiently disclosed the invention to enable the person skilled in the art to make and/or use the invention according to the M.P.E.P. guidelines.

Moreover, as stated above, the foregoing amends claim 2 to recite an isolated nucleic acid molecule comprising a polynucleotide of SEQ ID NO: 47. Further, claim 4 is amended to recite sequences that are complementary or reverse complement sequences to SEQ ID NO: 47 and are at least 30 nucleotides in length and confer vascular-preferred polynucleotide transcription.

Thus, the artisan skilled in the art, reading the specification, can readily identify and produce an isolated nucleic acid molecule comprising a polynucleotide having SEQ ID NO: 47 or a sequence that is complementary to SEQ ID NO: 47, or is a reverse complement to SEQ ID NO: 47 and is at least 30 nucleotides in length and confers vascular-preferred polynucleotide transcription. Accordingly, the claimed invention is fully enabled. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

III. The Rejection Under 35 U.S.C. § 102(b)

The Office Action, at pages 6-7, maintains the rejection of claim 4 under 35 U.S.C. § 102(b) as allegedly being anticipated by Polvere *et al.* (Genbank Accession No. U88240, 1997) ("Polvere"). The Office Action asserts that Polvere allegedly teaches a sequence comprising at

least 20 contiguous bases of SEQ ID NO: 47, and is therefore inherently complimentary to SEQ ID NO: 47. Applicants respectfully traverse this ground of rejection.

Solely to advance prosecution, and not in acquiescence with the rejection, the foregoing amends claim 4 to recite an isolated polynucleotide having a sequence that is complementary to SEQ ID NO: 47 or a sequence that is a reverse complement sequence to SEQ ID NO: 47. Further, claim 4 specifies that the complementary sequence and the reverse complement sequence to SEQ ID NO: 47 are at least 30 nucleotides in length and confer vascular-preferred polynucleotide transcription.

As previously stated, Polvere fails to disclose or suggest a complementary or reverse complement sequence to SEQ ID NO: 47 that is at least 30 nucleotides in length and confers vascular-preferred polynucleotide transcription. Thus, Polvere fails to anticipate the claimed invention.

For at least this reason, the rejection of claim 4 under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

IV. Other Matter

Claims 1 and 7-20 were previously cancelled pursuant an Election and Restriction Requirement. Applicants respectfully request that once the pending claims are found allowable, claims 1 and 7-20 be introduced into the application and rejoined in accordance with the provisions of the M.P.E.P., §821.04. Applicants further request that the requirement for restriction between the pending claims and the rejoined claims be withdrawn and the rejoined claims be fully examined for patentability, in accordance with 37 C.F.R. 1.104.

CONCLUSION

All of the stated grounds of rejection have been properly traversed or rendered moot. Thus, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date July 25, 2007

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